UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte PHILLIP W. BERMAN and LAURENCE A. LASKY

Appeal No. 2006-1822
Application 08/459,141

ON BRIEF

Before MILLS, GRIMES and LINCK, Administrative Patent Judges.

LINCK, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the final rejection of claims 10-23 and 25-41, all of the pending claims in Application No. 08/459,141 (hereafter the " '141 application"). The named inventors are Phillip W. Berman and Laurence A. Lasky, and the assignee is Genentech, Inc. The present application was filed on June 2, 1995 and thus has been pending in the Office for more than eleven years. The application claims a priority date of August 30, 1983. However, since Appellants filed a terminal disclaimer disclaiming

any term that extends beyond the term of U.S. Patent No. 5,851,533 (issued Dec. 22, 1998), if the '141 application issued, its exclusivity term would end Dec. 22, 2015. *See* Terminal Disclaimer dated Jan. 7, 1999.

Claim 10 is the broadest claim. It reads as follows:

> 10. An immunogenic composition comprising a truncated, membrane-free derivative of a polypeptide comprising a membrane-binding domain and antigenic determinants capable of raising neutralizing antibodies against in vivo challenge by a pathogen, wherein said derivative:
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> (a) is devoid of the membrane-binding domain whereby the derivative is free of membrane, and
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> (b) has exposed antigenic determinants capable of raising neutralizing antibodies against in vivo challenge by the pathogen.

The following references were cited and relied upon by the Examiner:

U.S. Patent No. 4,855,224 (issued Aug. 8, 1989 to Berman et al)(hereafter "'224 patent");

Watson et al., *Herpes simplex virus type-1 glycoprotein gene: nucleotide sequence and expression in E. coli*, 218 Science 381-84 (1982) (hereafter "Watson"); and

Dundarov et al., *Immunotherapy with inactivated polyvalent herpes vaccines*, 52 Developmental Biological Standards 351-58 (1982) (hereafter "Dundarov").

Claim 19 of the '224 patent (dependent on claim 13) is most relevant to the double-patenting analysis, as it is limited to truncated, membrane-free derivatives. It reads:

> 19. The diagnostic test kit of claim 13 [comprising:
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> (a) a diagnostic product comprising a membrane bound polypeptide with antigenic determinants capable of specifically binding complementary antibodies to herpes simplex virus, said polypeptide being formed in a recombinant, stable, continuous cell line; and
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> (b) a second component comprising either said complementary antibody or anti-antibody capable of specifically binding said complementary antibody]
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> in which said diagnostic product is a truncated, membrane-free derivative of a polypeptide, said derivative being devoid of a membrane binding domain whereby the derivative is free of said membrane.

The Outstanding Rejections

Claims 10-12, 14-19, 25-29 and 32-41 stand rejected under the judicially-created doctrine of obviousness-type double patenting over claims 1-5, 9, 13, 19, 20, 21, 25 and 26 of the '224 patent. From March 2002 until November 2005, only claims 13, 19 and 20 of the '224 patent were cited; claims 1-5, 9, 21, 25 and 26 were added to this ground of rejection in the Examiner's Answer. [1] See Answer at 3. Further, there is no evidence that the language of any of the '224 claims was ever compared to the pending claims during prosecution. *See* the Office Actions dated 3-15-02 and 12-16-02. Rather the claims were first compared in the Answer. *See* Answer at 11-12. In the Answer, the Examiner compared claim 10 of the '141 application with claims 13 and 19 of the '224 patent. *Id.*

Claims 10-23 and 25-41 (all pending claims) stand rejected for obviousness-type double patenting over claims 1-5, 9, 13, 19, 20, 21, 25 and 26 of the '224 patent in view of Watson and Dundarov. Again, from March 2002 until November 2005, only claims 13, 19 and 20 of the '224 patent were cited against the pending claims, with claims 1-5, 9, 21, 25 and 26 being added to this second ground of rejection in the Examiner's Answer. See Answer at 7. With respect to this ground of rejection, the Examiner did not conduct any additional claim comparisons. See Answer *passim*.

We reverse.

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[1] While the Appellants have not objected to this irregular procedure, perhaps to avoid further delays in this case, technically the appeal is from the final rejection and should not be supplemented in the answer. See *In re Webb*, 916 F.2d 1553, 1556, 16 USPQ2d 1433, 1435 (Fed. Cir. 1990) ("an examiner's final rejection, which precipitates the statutory right to appeal to the Board . . . constitutes the 'decision' of an examiner for purposes of § 1.196(a)").

BACKGROUND

> Analysis of the immune response to a variety of infectious agents has been limited by the fact that it has often proved difficult to culture pathogens in quantities sufficient to permit the isolation of important cell surface antigens. The advent of molecular cloning has overcome some of these limitations by providing a means whereby gene products from pathogenic agents can be expressed in virtually unlimited quantities in a non-pathogenic form. . . . It is clear, however, that the expression of surface antigens in lower organisms is not entirely satisfactory in that potentially significant antigenic determinants may be lost by virtue of incomplete processing . . . or by denaturation during the purification of the cloned gene product.
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> This is particularly true in the case of membrane proteins, which . . . tend to aggregate and become insoluble when expressed in E. coli. . . . While . . . studies show that membrane proteins can be expressed on the surface of a recombinant host cell, and . . . a truncated membrane protein lacking the hydrophobic carboxy-terminal domain can be slowly secreted from the host cell rather than be bound to it, it is not clear that either . . . will be able to act, in fact, to raise antibodies effective against the pathogen from which the protein is derived.
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> Herpes Simplex Virus (HSV) is a large DNA virus which occurs in two related, but distinguishable, forms in human infections. . . . [G]lycoproteins, termed gA/B, gC, gD, and gE, are found in both HSV type 1 (HSV 1) and HSV type 2 (HSV 2), while in the case of HSV 2, an additional glycoprotein (gF) has been reported . . . . Although their functions remain somewhat of a mystery, these glycoproteins are undoubtedly involved in virus attachment to cells, cell fusion, and a variety of host immunological responses to virus infection. [Specification at 1-2 (citations omitted).]

The invention disclosed in the '141 application is a vaccine comprising a truncated, membrane-free derivative of a polypeptide with antigenic determinants "capable of specifically raising complementary antibody against HSV-1 and HSV-2 viruses." *Id.* at 5. The derivative can be "formed by omission of a membrane-binding domain from the polypeptide, allowing it to be secreted from the recombinant host cell system in which it has been produced." *Id.* Alternatively, the polypeptide can be

"formed first in functional association with a surface membrane and thereafter the polypeptide is dissolved, preferably in a non-ionic surfactant, to free the polypeptide of the membrane." *Id.* at 6. While the disclosure focuses on a vaccine for HSV, the broadest claim is not so limited but instead covers "antigenic determinants capable of raising neutralizing antibodies against in vivo challenge" by any pathogen. See claim 10.

DISCUSSION

Obviousness-Type Double Patenting

The two grounds of rejection in this case are based on the judicially-created doctrine of obviousness-type double patenting. Final Office Action at 3-4 (mailed Dec. 16, 2002). In reviewing these rejections, we must consider whether the Examiner has *prima facie* established that the pending claims are merely to an obvious variation of, or not patentably distinct from, subject matter previously claimed in the commonly-owned '224 patent. *See, e.g., In re Longi*, 759 F.2d 887, 892, 225 USPQ 645, 648 (Fed. Cir. 1985). The purpose of this judicially-created doctrine is to prevent "*improper* timewise extension of the patent right by prohibiting the issuance of claims in a second patent which are not 'patentably distinct' from the claims of a first patent." *In re Braat*, 937 F.2d 589, 592, 19 USPQ2d 1289, 1292 (Fed. Cir. 1991) (emphasis in orginal) (citations omitted). *See also, e.g., In re Kaplan*, 789 F.2d 1574, 1577-78, 229 USPQ 678, 681-82 (Fed. Cir. 1986). Thus, the focus is necessarily on the claims:

> Generally, an obviousness-type double patenting analysis entails two steps. First, as a matter of law, a court construes the claim in the earlier patent and the claim in the later patent [or application] and determines the differences. . . . Second, the court determines whether the differences in subject matter between the two claims render the claims patentably distinct. . . . A later patent [or application] claim is not

> patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim. [*Eli Lilly & Co. v. Barr Labs*, 251 F.3d 955, 968, 58 USPQ2d 1869, 1878 (Fed. Cir. 2001).]

While the specification can be used "as a dictionary to learn the meaning of terms in a claim," it is *the claims* that must be compared. Further, "dominance" must not be confused with double patenting. A generic or broad claim may issue first, followed by the issuance of a more specific claim, "the former 'dominating' the latter because the more narrowly claimed invention cannot be practiced without infringing the broader claim. . . . This commonplace situation is not, per se, double patenting . . . ." *Kaplan,* 789 F.2d at 1577, 229 USPQ at 681. This is so even if the later-claimed, more specific subject matter is disclosed in the earlier to issue patent. *See, e.g., id.*; *In re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622-23 (CCPA 1970). *See also* Reply at 5-6 for a discussion of *Kaplan*. Thus, the fact that the "subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent," as the Examiner found (Answer at 7), is not sufficient alone to reject the claims under the judicially-created doctrine of double patenting.

The Prosecution History

The '141 application was filed on June 2, 1995 and was diligently pursued during the 11 year period it has been pending. Thus, this is not a case in which Appellants have unduly delayed to extend their patent term. To overcome a double patenting rejection made in 1997 based on two earlier cases (not the '224 patent), Appellants abandoned one case and filed a terminal disclaimer to overcome the rejection in the other.

In view of this action, the '141 application was allowed in January 1999. Notice of Allowance, dated 1-22-99. But then it was withdrawn from issue in December 1999 "due to the unpatentability of one or more claims." Notice of Withdrawal from Issue, dated 12-28-99. While the application was abandoned for a brief period of time, Appellants promptly sought revival and terminally disclaimed any term they would have gained through the abandonment. See Petition to Revive with Terminal Disclaimer, dated 1-27-04, and Decision on Petition, dated 6-23-04.

The Cited Patent and Prior Art References

The '224 patent is the only cited reference with respect to the first ground of rejection and the primary reference with respect to the second ground. It issued August 8, 1989 and expired August 8, 2006. All of the '224 patent claims are directed to a diagnostic product or a diagnostic test kit for detecting HSV, and all except claims 19-21 are limited to "membrane-bound" polypeptides. See the '224 patent, col. 32, line 18-col. 34, line 53. In claims 19-21, the "diagnostic test kit" utilizes a "diagnostic product" that is a "membrane-free derivative of a polypeptide." Col. 33, lines 13-28. Only claims 19 and 20 require that the derivative be "truncated" and "devoid of a membrane-binding domain." Col. 33, lines 13-23. The '224 claims require "antigenic determinants capable of specifically binding complementary antibodies to herpes simplex virus" but do not require "antigenic determinants capable of raising neutralizing antibodies against in vivo challenge" by a pathogen.

The Examiner relies heavily (in fact almost exclusively) upon the diagnostic product of Example 3 disclosed in the '224 patent. *See* Answer at 4-10 & 13-18. This product admittedly "contains 'exposed antigenic determinants capable of raising

neutralizing antibodies against in vivo challenge by the pathogen,' as recited in the pending claims." Reply at 5. In fact, Example 3 is repeated almost verbatim in the pending application. *See* '141 application at 22-27. Example 3 is included in the '224 patent to illustrate "the removal of the membrane from the expressed membrane-bound protein." Col. 17, lines 46-47. "The advantages of using the truncated protein for diagnostic applications is that, being secreted into the extracellular medium, it is contaminated with far fewer proteins than would be found in a whole-cell preparation." *Id.* at col. 20, lines 51-55.

The Watson article was published in October 1982 and states:

> Embedded within the virion envelope, which is derived from the cellular lipid bilayer during maturation of the virus, are five major HSV-specified glycoproteins, designated gA, gB, gC, gD, and gE. . . . Antiserums to each of these glycoproteins [the five major ones] can neutralize infectivity of the homogenous HSV type in an *in vitro* assay. [Watson at 381 (col. 1) (citations omitted).]

This language in Watson is relied upon to show that "herpes glycoproteins gA, gB, gC, gD, and gE are able to elicit neutralizing immune responses in an animal." Answer at 18. It is further relied upon to support the Examiner's conclusion that "it would have been obvious to formulate a polyvalent vaccine because it was known that *all* HSV glycoproteins elicit a neutralizing response." Answer at 19 (emphasis added); *see also* Answer at 8 ("antibodies to *all* of the glycoproteins are capable of neutralizing infection" (emphasis added). However, this conclusion is not well supported by Watson. See the quoted language above ("major" implying others exist). *See also* the '224 specification at col. 5, lines 44-47 (other glycoproteins "not yet identified . . . may be used for diagnostic products").

The Dundarov article was published in 1982 and is relied upon to show "the production of a polyvalent whole virus vaccine" which "comprises five different strains of HSV-1 and five different strains of HSV-2, thereby teaching the use of a polyvalent mixture comprising HSV glycoproteins." Answer at 9.

The Differences Between the '224 Patent Claims and The Claimed Invention

The '224 patent claims are directed to diagnostic products and diagnostic test kits for detecting HSV. Most relevant here, the claimed diagnostic product is a "truncated, membrane-free derivative" of a polypeptide "capable of specifically binding complementary antibody to herpes simplex virus." See claim 19 of the '224 patent (in which the diagnostic product is claimed as one component of a diagnostic test kit). The broadest '141 application claim, claim 10, is directed to an "immunogenic composition comprising a truncated, membrane-free derivative of a polypeptide" having "antigenic determinants capable of raising neutralizing antibodies against in vivo challenge by the pathogen."

We view these two claims as having two potentially significant differences. First, claim 19 of the '224 patent is limited to HSV while pending claim 10 covers any pathogen.[2] If this difference were the only difference between the two claims, the HSV subgenus would clearly fall within and anticipate the pathogen genus of claim 10.

[2] Some of the narrower claims are limited to HSV, for example, claim 25.

Anticipation of the pathogen genus by the HSV subgenus would not be negated by the presence of additional kit components in claim 19. *See, e.g., Lilly*, 251 F.3d at 970, 58 USPQ2d at 1880 ("A reference is anticipatory if it discloses every limitation of the claimed invention either explicitly or inherently"). Thus, if this difference were the only difference, an obviousness-type double patenting rejection would be appropriate, absent the need to apply a two-way test.[3] *See, e.g., In re Berg*, 140 F.3d 1428, 1437, 46 USPQ2d 1226, 1233 (Fed. Cir. 1998) (affirming a holding of obviousness-type double patenting where a patent application claim to a genus is anticipated by a patent claim to a species).

Second, claim 19 of the '224 patent requires that its diagnostic products bind to complementary antibodies, while pending claim 10 requires that its immunogenic products raise neutralizing antibodies. *Compare* claim 19 *with* claim 10. In our view, this second potential difference is key to our determination. *If* these two genera are of the same scope or if claim 19's diagnostic product genus is a subgenus of claim 10's immunogen genus, then claim 19's diagnostic product genus anticipates claim 10's immunogen genus. In other words, if *all* of the diagnostic products covered by claim 19 inherently raise neutralizing antibodies, then they inherently anticipate the immunogenic products of claim 10. Such a situation would support an obviousness-type double patenting rejection.

[3] We see no evidence in this case suggesting the two-way test is required.

Obviousness-Type Double Patenting Applied to the Pending Claims

Obviousness-type double patenting cannot be determined without a comparison of the claims. *See, e.g., In re Kaplan*, 789 F.2d at 1577-78, 229 USPQ at 681-82. Given the lack of any claim comparison between claims 2, 3, 5, 9, 20, 21, 25 and 26 of the '224 patent and the pending claims, the Examiner has failed to make a *prima facie* case of obviousness-type double patenting with respect to these issued claims. Further, issued claims 1-5, 9, 13, 25 and 26 require a membrane-bound polypeptide.[4] As the Examiner has not made any argument or provided any evidence that it would have been obvious to modify the claimed membrane-bound polypeptides in these claims to make the truncated, membrane-free polypeptides of the pending claims, she has failed to make a *prima facie* case of obviousness-type double patenting based on these issued claims. Thus, we turn to claim 19 of the '224 patent (which includes a truncated, membrane-free polypeptide) to determine whether the Examiner has made a *prima facie* case of double patenting with respect to pending claim 10 based on this claim.

Claim 10 of the '141 application recites a genus of truncated, membrane-free derivatives having "exposed antigenic determinants capable of raising neutralizing antibodies against in vivo challenge by the pathogen." Claim 19 of the '224 patent recites a genus of truncated, membrane-free derivatives "capable of specifically binding complementary antibodies to herpes simplex virus." Comparing these two claims, the key issue is, has the Examiner made a *prima facie* case that claim 10 is anticipated or

[4] The Examiner argues that the derivatives in claims 4 and 5, to a "fragment of glycoprotein C," are membrane-free. Answer at 18. We disagree with this interpretation, as it is not supported by the claim language or the specification. *See* the '224 patent, col. 5, lines 30-43.

would have been obvious over claim 19? In our view, based on the record before us, the answer to this question is "no."

The Examiner bases her case of obviousness-type double patenting primarily on a comparison of an embodiment of the '224 patent's claim 19 with an embodiment of the '141 application, concluding that they are the same. *See* Answer *passim*. She does not construe any claims or make any claim comparison until her Answer and even then focuses on the '224 specification rather than the claims. *Id.*

The Examiner supports her reliance on the '224 specification as follows:

> "The specification can always be used as a dictionary to learn the meaning of a term in the patent claim." *In re Boylen*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). The term "diagnostic product" and the "fragment of a glycoprotein" needed to be looked up in the specification in order to understand the structure of the claimed invention in '224. In order to understand the term "devoid of membrane-binding domain" the meaning also needed to be looked up in the specification.
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> . . . .
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> *In re Vogel* allows the inspection of the patented specification in order to determine the structure of at least one tangible embodiment that falls within the patented claim. This portion of the specification is not considered prior art. It is easier to compare a tangible embodiment. The tangible embodiment that "comprises a membrane free derivative of the polypeptide" of the '224 patent is found in example[s] 1, 2 and 3 of '224. [Answer at 13-14.]

While agreeing with the Examiner that *Vogel* is "governing law," Brief at 6, Appellants explain at length how the Examiner has inappropriately used the '224 specification in this case. *See* Brief at 6-11. Basically, Appellants argue that only the portion of the specification necessary to support the diagnostic claims can be referenced. We find Appellants' analysis consistent with *Vogel*. *See* 422 F.2d at 441-42, 164 USPQ at 622 ("those portions of the specification *which provide support for the patent claims*

may also be examined and considered") (emphasis added). Thus, any teaching regarding the use of Example 3 as an immunogen must be disregarded.

The Examiner erred in her heavy reliance on the '224 specification. While the Examiner is correct that one can use the specification as a dictionary to determine what claim terms mean, the Examiner's use of the examples, particularly Example 3, goes beyond such permitted use and treats the examples as prior art. The Examiner's own statements make this clear: "The mere recitation of newly-discovered function (capable of raising neutralizing antibodies) or property, inherently possessed by things *in the prior art*, does not cause the claim drawn to those things to distinguish *over the prior art* . . . ." Answer at 6 (emphasis added). Here, Example 3 is *not* "in the prior art." Significantly, the Examiner does not identify and apply the meaning of any claim terms garnered from the specification. While it is clearly appropriate under *Vogel* to use the specification to identify a tangible embodiment *within* a claim, the analysis cannot stop there, as the scope of the claims must be compared in determining obviousness-type double patenting.

In *Kaplan*, the Federal Circuit explained the *Vogel* court's limitation of the use of the specification: "The second question, according to *Vogel*, is: 'Does any claim in the application define merely an obvious variation of an invention disclosed and claimed in the patent? In considering the question, the patent disclosure may not be used as prior art.'" 789 F.2d at 1579, 229 USPQ at 682. Again, we believe that is what the Examiner has done in this case. Rather than focusing on the claims and the differences between them, the Examiner has chosen to rely on an embodiment in the '224 specification. Thus, she has compared a species that may be covered by the generic '224 claims rather than

comparing the generic claims themselves. *See, e.g.,* Answer at 5 (referencing Example 3 in the '224 specification).

The Examiner repeatedly (and tellingly) states that the "*structure* of the prior patent '224 is the same as the *structure* claimed in the present invention." Answer at 9 (emphasis added); see also Answer at 4, 5, 7, 16 & 17. Such language and analyses do not support an obviousness-type double patenting rejection in which the claims must be compared. We find no allegation or argument that the scope of the *claimed* diagnostic product genus in any of the '224 patent claims is the same as that of the *claimed* immunogenic product genus, or that the *claimed* diagnostic product genus falls within that of the *claimed* immunogenic product genus. And Appellants argue to the contrary:

> [T]he Examiner's conclusion that the two [polypeptide derivatives] are structurally identical is . . . incorrect. The Examiner's conclusion appears to be based on the assumption that the same antigenic determinants that bind complementary antibody will also be capable of producing an in vivo neutralizing antibody response. . . . This rationale ignores the well-known scientific reality that only some antigenic determinants are neutralizing determinants. In other words, proteins typically contain multiple sites that bind complementary antibody. These are termed "antigenic determinants" or "epitopes." Some or one or none of these sites may be capable of eliciting an in vivo neutralizing antibody response against a pathogen. Sites that do have this capability, if any, are termed "neutralizing antigenic determinants" or "neutralizing epitopes." Thus, if a particular protein is shown to have 20 sites that bind complementary antibody, it may be that only one such site is a neutralizing antigenic determinant. If, for example, the neutralizing antigenic determinant is the most amino-terminal determinant, the requirement that a derivative of the protein be capable of eliciting an *in vivo* neutralizing antibody response dictates that the derivative must contain that amino-terminal neutralizing determinant. By contrast, the requirement that the derivative be capable of binding complementary antibody simply requires that the derivative contain at least one of the 20 antigenic determinants scattered throughout the protein. This hypothetical makes it absolutely clear that the genus of derivatives capable of eliciting an *in vivo* neutralizing response defines a structurally different set of molecules than that defined by the genus

> of derivatives capable of binding complementary antibody. [Reply at 4-5; see also Brief at 5-6 (quoting earlier response).]

Further, the Examiner fails to make a case that claim 10's immunogen genus would have been obvious in view of claim 19's diagnostic kit genus. While inherency can be used to support anticipation, or even obviousness in certain cases, the Examiner's application in this case is not appropriate. *See, e.g., In re Spormann,* 363 F.2d 444, 448, 150 USPQ 449, 452 (CCPA 1966), *quoted in In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) ("Obviousness cannot be predicated on what is unknown."). Thus, with respect to determining obviousness-type double patenting based on obviousness rather than anticipation, a finding of some suggestion or motivation to modify claim 19's diagnostic kit to obtain claim 10's immunogen would be required. *See* Brief at 7-13; Reply at 3-4 & 6-7. The Examiner has not made such a finding. *See* Answer at 13.

The Examiner also relies upon *In re Best*, 195 USPQ 430, 562 F.2d 1252 (CCPA 1977). Under *Best*, according to the Examiner, "if the claimed and prior art products are identical or substantially identical, the USPTO can require an applicant to prove that the prior art product does not necessarily or inherently possess the characteristics of the claimed product." Answer at 10.

In the context of a prior art rejection under § 102 or 103, the application of *Best* may be appropriate. The claims in *Best* were to a zeolite and a process for making the zeolite. 562 F.2d at 1253, 195 USPQ at 432. While the claims were generic, just as the ones in this case, the rejection in *Best* was under § 102, or alternatively § 103. *Id.* Thus, in *Best,* the Examiner was not required to compare the pending claims to those of an

issued patent. Rather he only had to identify one prior art species within the pending claim to find anticipation. Here, it is not disputed that one species falls within the scope of claim 19 and claim 10. However, that fact alone does not establish double patenting. Rather, the claims must be compared. Thus, *Best* is not on point.

Further, even if we were to extend the reasoning in *Best* to the facts of this case, the Examiner has not provided sufficient evidence that the claims are of the same or substantially the same scope. As noted by the Examiner, "in order to invoke the principles of *In re Best*, the examiner must first make factual findings which support the conclusion that the claimed and prior art products *prima facie* are 'identical or substantially identical.'" Answer at 10. Extending this analysis to a double-patenting case would require the Examiner to make findings supporting the conclusion that the claimed immunogen genus and the claimed diagnostic product genus *prima facie* are identical or substantially identical. The Examiner has offered a single piece of evidence to support this conclusion—the undisputed overlap of one species. That single piece of evidence is not sufficient to shift the burden to Appellants in view of their arguments to the contrary. *See* Reply at 4-5 (quoted *supra* at 14-15).

With respect to the second ground of rejection based on the '224 patent in view of Watson and Dundarov, the Examiner's approach was substantially the same. *See* Answer at 19-21. In addition to her earlier arguments, with respect to Watson, she stated:

> Watson et al. established that HSV glycoproteins A-E were known at the time the instant invention was filed. These glycoproteins were also known at that time to produce neutralizing antibodies. Thus, membrane-free derivatives of all known glycoproteins are obvious because the '224 claims are broadly drawn to all membrane-free derivatives of HSV glycoproteins. [Answer at 20.]

We note several errors in the Examiner's reasoning with respect to Watson. First, many of the '224 claims, including claim 19, are not limited to glycoproteins but instead cover all polypeptides. Second, her analysis ignores the fact that the pending claims are to truncated, membrane-free derivatives, while those disclosed in Watson are not. Thus, her conclusion does not necessarily follow. Lacking a claim-by-claim determination and an analysis addressing the claimed genera, we find the same deficiencies for the second ground as we do for the first.

Given that the Examiner has failed to make a *prima facie* case of obviousness-type double patenting with respect to claim 10, the broadest pending claim, it is not necessary for us to address the remaining pending claims of more limited scope. Thus we reverse the outstanding rejections with respect to all the pending claims.

Other Issue

For the reasons discussed above, we conclude that the Examiner's rejection cannot be sustained. However, the evidence of record suggests that the genus of polypeptides recited in claim 19 of the '224 patent may be a subgenus of the polypeptides recited in instant claim 10. If so, a double patenting rejection of at least the claims covering all pathogens (claims 10, 14, 15, 16, 17, 32, 35, 36, 37, 38, 39) may be appropriate.

The '224 patent's claim 13 (on which claim 19 depends) is directed to a kit that includes "a membrane-bound polypeptide with antigenic determinants capable of specifically binding complementary antibodies to herpes simplex virus." This limitation reasonably appears to define membrane-bound herpes simplex virus (HSV) proteins,

since only HSV proteins would be expected to be specifically bound by antibodies to HSV.

Watson states that "[e]mbedded within the virion envelope, which is derived from the cellular lipid bilayer . . . , are five major HSV-specified glycoproteins, designated gA, gB, gC, gD, and gE." Watson at 381, left-hand column. Watson also states that "[a]ntiserums to each of these glycoproteins can neutralize infectivity of the homologous HSV type in an in vitro assay." *Id.*

This disclosure may support a conclusion that each of the five major HSV glycoproteins has "antigenic determinants capable of specifically binding complementary antibodies to" HSV. *If* these glycoproteins are the only membrane-bound HSV proteins with this property, then the genus of polypeptides defined by the '224 patent's claim 13 may consist of only five proteins.[5]

In addition, each of those HSV glycoproteins was known, as of the '141 application's effective filing date, to display antigenic determinants capable of "neutraliz[ing] infectivity of the homologous HSV type in an in vitro assay." Watson at 381, left-hand column. Watson also states that antiserum to gD "protected against acute neurological disease induced by either HSV-1 or HSV-2" in mice *in vivo*. *Id.* at 381, middle column. Thus, all five membrane-bound glycoproteins raised antibodies that were neutralizing *in vitro*, and gD raised antibodies that were neutralizing *in vivo*. Based on this evidence, it may be reasonable to conclude that all five HSV envelope

[5] We note, however, that both the '224 specification and Watson suggest otherwise. See '224 specification at col. 5, lines 44-47 (other glycoproteins "not yet identified . . . may be used for diagnostic products"); Watson at 381 (use of the term "major" implying there are others). This evidence must be considered.

glycoproteins have antigenic determinants capable of raising neutralizing antibodies against *in vivo* challenge by HSV.

The '224 patent's claim 19 also requires that the polypeptide included in the diagnostic kit is "devoid of a membrane-binding domain whereby the derivative is free of . . . membrane." Thus, claim 19 of the '224 patent may be limited to HSV glycoproteins (gA, gB, gC, gD, or gE) as defined by claim 13, truncated so as to delete the membrane-binding domain. If claim 19 is so limited, it would define a set of polypeptides that are a subgenus of those defined by instant claim 10; i.e., claim 19 may be limited to HSV glycoprotein derivatives, while claim 10 encompasses polypeptides derived from any pathogen.

If in fact the polypeptides defined in the '224 patent's claim 19 are a subgenus of those defined by instant claim 10, then claim 19 differs from claim 10 only in requiring the further presence of a "complementary antibody or anti-antibody" as well as the polypeptide. If the only difference between claim 10 and claim 19 is the presence of a "complementary antibody or anti-antibody," then claim 19 would anticipate claim 10. In our view, a double patenting rejection may be appropriate in such a situation. *See* Lilly, 251 F.3d at 968, 58 USPQ2d at 1878 ("A later patent claim is not patentably distinct from an earlier patent claim if the later claim is . . . anticipated by[] the earlier claim."). *See also* the discussion *supra* at 9-10.

On return of this application, we recommend that the Examiner focus on the claims rather than the examples in the specification and consider: (1) the scope of the polypeptides defined by claim 19 of the '224 patent, including whether the glycoproteins designated gA, gB, gC, gD and gE are the only membrane-bound HSV proteins having

"antigenic determinants capable of specifically binding complementary antibodies to" HSV, in view of the evidence that there are other HSV glycoproteins (see footnote 5) and in view of the language of claim 19 which is not limited to glycoproteins; (2) whether the evidence of record reasonably shows or suggests that the truncated, membrane-free polypeptides encompassed by claim 19 of the '224 patent would be likely to raise neutralizing antibodies *in vivo*; and (3) whether the complementary antibody or anti-antibody required by the claims of the '224 patent makes those claims patentably distinct from the instant claims, taking into consideration the statement in *Lilly* (quoted below).

If the examiner concludes that the polypeptides of the '224 patent's claim 19 are a subgenus of those defined by instant claim 10, and that the complementary antibody or anti-antibody required by the '224 patent's claims does not make those claims patentably distinct from the instant claims, a rejection on that basis, of at least some of the instant claims for obviousness-type double patenting may be appropriate. *See Lilly*, 251 F.3d at 968, 58 USPQ2d at 1878 ("A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim."); *id.* at 971, 58 USPQ2d at 1880 ("[A] later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim.").

This application has been pending at the Office for eleven years, and we regret causing any further delays in prosecution. Nonetheless, we believe that the issue

discussed above should be fully considered by the Examiner before the application is allowed to issue as a patent.

REVERSED

DEMETRA J. MILLS
Administrative Patent Judge

ERIC GRIMES
Administrative Patent Judge

NANCY J. LINCK
Administrative Patent Judge

BOARD OF PATENT APPEALS AND INTERFERENCES

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